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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/349,479	12/02/1994	WAYNE A. BORDER	PLA1245	6468
23601	7590	06/29/2004	EXAMINER	
CAMPBELL & FLORES LLP 4370 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122			GAMBEL, PHILLIP	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 08/349,479	<b>Applicant(s)</b> BORDER ET AL.	
	<b>Examiner</b> Phillip Gambel	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.  
2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21 and 35 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 21 is/are allowed.  
6) ☒ Claim(s) 35 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's amendment, filed 2/20/04, has been entered.

Claims 21 and 35 are currently and being acted upon presently.

Claims 1-20 and 22-34 have been canceled previously.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. This Action will be in response to applicant's arguments, filed in 2/20/04. The rejections of record can be found in the previous Office Action.

3. Upon reconsideration of applicant's arguments, filed 2/20/04, the previous rejection with respect to claim 21 under 35 U.S.C. § 103(a) as being unpatentable over Dasch et al. (U.S. Patent No. 5,772,998) in view of Ruoslahti et al. (U.S. Patent No. 5,583,103) AND/OR Bassols et al. (J. Biol. Chem. 263: 3039-3045, 1988) has been withdrawn.

The prior art priority document USSN 07/212,702 for Ruoslahti et al. (U.S. Patent No. 5,583,103) nor Bassols et al. do not provide sufficient teachings and motivation with respect to the role of TGF- $\beta$  as responsible, at least in part, for glomerulonephritis and, in turn, for applying TGF- $\beta$ -specific antibodies in the treatment of glomerulonephritis. Dasch et al. differs from the claimed methods by not disclosing that TGF- $\beta$  was responsible, at least in part, for glomerulonephritis.

4. Claim 35 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Dasch et al. (U.S. Patent No. 5,772,998) in view of Bassols et al. (J. Biol. Chem. 263: 3039-3045, 1988) and Raghu et al. (Am Rev Respir Dis 131: 281-29 (1985).

Applicant's arguments, filed 2/2/04, have been fully considered but are not found convincing essentially for the reasons of record.

Once a prima facie case of obviousness has been made the burden of going further is shifted to applicant. In re Keller, 642 F.2d 4B, 208 USPQ 871, 882 (CCPA 1981). This applicant has not done, but rather argues the references individually and not their combination. One cannot show non-obviousness by attacking references individually where the rejections are based on a combination of references. In re Young 403 F.2d 759, 150 USPQ 725 (CCPA 1968). See MPEP 2145.

Although applicant asserts that Dasch et al. makes no reference to ARDS, it has been noted that Dasch et al. does teach the use of TGF- $\beta$ -specific antibodies to neutralize the effects of TGF- $\beta$ , including various fibrotic conditions such as lung fibrosis (see entire document, including columns 5-6 and the Claims). Although Dasch et al. teach treating interstitial lung fibrosis, Dasch et al. differs from the claimed methods by not disclosing targeting ARDS per se.

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Although applicant asserts that Bassols et al. does not teach or suggest the use of any agent to treat ARDS, it has been noted that Bassols et al. does teach TGF- $\beta$  regulates the expression of the extracellular matrix chondroitin/dermatan sulfate proteoglycans (see entire document, including Abstract, pages 3041 and 3043), including that TGF- $\beta$  regulates proteoglycans in lung epithelial cell and fibroblast proliferation (see pages 3040-3041).

Although applicant asserts that Raghu et al. does not teach the involvement of TGF- $\beta$  in ARDS, it has been noted that in reviewing the role of the extracellular matrix in the pathogenesis of interstitial pulmonary fibrosis, Raghu et al. teach that interstitial fibrosis was a characteristic feature of ARDS (see entire document, including Introduction and Summary on page 281).

Given the teachings of Dasch et al. that TGF- $\beta$ -specific antibodies could neutralize the effects of TGF- $\beta$  in a several disorders; one of ordinary skill in the art at the time the invention was made would have motivated to apply such TGF- $\beta$ -specific antibodies in other fibrotic disorders, such as interstitial lung fibrosis (see Dasch et al.) and ARDS, wherein interstitial fibrosis is a characteristic feature (see Raghu et al.). Similarly, given the role of the extracellular matrix in interstitial lung fibrosis and ARDS (see Dasch et al. and Raghu et al.) and the ability of TGF- $\beta$  to stimulate lung epithelial cell and fibroblast proliferation, one of ordinary skill at the time the invention was made would have had a reasonable expectation that neutralizing TGF- $\beta$  with TGF- $\beta$ -specific antibodies would be effective in treating fibrotic diseases, including ARDS. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments are not found persuasive.

5. Upon reconsideration of applicant's arguments, filed 2/20/04, the previous rejection of claims 21 and 35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dasch et al. (U.S. Patent No. 5,772,998) in view of Ruoslahti et al. (U.S. Patent No. 5,583,103) AND/OR Bassols et al. (J. Biol. Chem. 263: 3039-3045, 1988) for the reasons of record as it applies to claim 21 AND/OR over Dasch et al. (U.S. Patent No. 5,772,998) in view of Bassols et al. (J. Biol. Chem. 263: 3039-3045, 1988) and Raghu et al. (Am Rev Respir Dis 131: 281-29 (1985) for the reasons above set forth in Section 5 as it applies to claim 35 and in further evidence of applicant's admission that given a generic method of decreasing TGF- $\beta$ -induced production and deleterious accumulation of extracellular matrix associated with a pathology or a condition would render the specific fibrotic disorders such as glomerulonephritis, ARDS, cirrhosis or the liver and scarring as obvious species of one another (see Brief on Appeal, particularly Regarding Species Claims 23 and 25 and Regarding Genus Claim 21 on pages 18-24 of the Brief on Appeal, filed 3/11/02 (Paper No. 80) and page 13 of the Reply Brief, filed 8/9/02 (Paper No. 82) has been withdrawn.

6. Claim 21 appears free of the prior art.

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**7. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, PhD.  
Primary Examiner  
Technology Center 1600  
June 25, 2004